510(K) SUMMARY

In accordance with 21 CFR 807.92

K062905

1. Date of preparation

`eptember 25, 2006

2. Company information

BarcoView
35 President Kennedypark
B-8500 Kortrijk, Belgium
Tel. +32-(0)56-233-211
Fax +32-(0)56-233-457

DEC 29 2006

3. Contact person

Lieven De Wandel
Official correspondent

4. Device information

- Trade name: MDNC 4130
- Common name: Display system, medical image workstation, and others
- Classification name: System, Image Processing
- Classification number: 21 CFR 892.2050 / Procode 90LLZ

5. Predicate device

- Name: E-2320 C
- 510(k) number: K052958
- Manufacturer: Barco NV

6. Device description

MDNC 4130 is a 30" color LCD display for medical viewing. It is combined with MediCal QAWeb, a user-friendly software that allows to optimize the display for DICOM-compliant viewing.

7. Intended use

"The MDNC 4130 is intended to be used in displaying and viewing digital images, for review and analysis by trained medical practitioners. These devices must not be used in primary image diagnosis in mammography. The MDNC 4130, which is part of the Nio Fusion 4MP system, will e marketed separately.

8. Summary of technological characteristics

The flat panel display panel has a resolution of 2560x1600 pixels. In Single View mode, the display is driven as one 4-megapixel desktop, in DuoView mode, the display is driven via 2 DVI inputs as two separate 2-megapixel desktops.

The MediCal QAWeb software allows to set the display function, display test patterns, calibrate the display and view additional display and display controller information.

Compared to the predicate device, the MDNC 4130 display uses a larger LCD panel and modified electric circuits. However, the basic functions and intended use of both displays are the same.

The device does not come into contact with the patient. It does not control any life-sustaining devices either.

9. Conclusion:

The Barco MDNC 4130 is substantially equivalent to the predicate device, E-2320 C.

The new and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application and intended use.

Any difference between both devices does not affect safety or efficacy.

The 510(k) Pre-Market Notification for the Barco MDNC 4130 contains adequate information and data to enable FDA – CDRH to determine substantial equivalence to the predicate device.

510(K) SUMMARY

In accordance with 21 CFR 807.92

1. Date of preparation

September 25, 2006

2. Company information

BarcoView
35 President Kennedypark
B-8500 Kortrijk, Belgium
Tel. +32-(0)56-233-211
Fax +32-(0)56-233-457

3. Contact person

Lieven De Wandel
Official correspondent

4. Device information

- Trade name: Nio Fusion 4MP
- Common name: Display system, medical image workstation, and others
- Classification name: System, Image Processing
- Classification number: 21 CFR 892.2050 / Procode 90LLZ

5. Predicate device

- Name: Color Nio 2MP
- 510(k) number: K052958
- Manufacturer: Barco NV

6. Device description

Nio Fusion 4MP is a display system for medical viewing. It consists of 3 components:
MDNC 4130 is a 30" color LCD display. MXRT 2100 is a fast high-resolution display controller board that plugs into a PACS workstation computer. MediCal QAWeb is a softcopy QA software application for local calibration and QA control.

7. Intended use

The Nio Fusion 4MP is intended to be used in displaying and viewing digital images, for review and analysis by trained medical practitioners. These devices must not be used in primary image diagnosis in mammography.

8. Summary of technological characteristics

The device consists of three components:

- One 4-megapixel flat panel display (MDNC 4130)
- One 32-bit display controller (MXRT 2100 board)
- MediCal QAWeb software

The flat panel display panel has a resolution of 2560x1600 pixels. In Single View mode, the display is driven as one 4-megapixel desktop, in DuoView mode, the display is driven via 2 DVI inputs as two separate 2-megapixel desktops.

The MXRT 2100 display controller board is an ultra-high-speed board with a 32-bit in, 32-bit out lookup table, providing up to 64 bit color.

The MediCal QAWeb software allows to set the display function, display test patterns, calibrate the display and view additional display and display controller information.

Compared to the predicate device, the display of the Nio Fusion 4MP system uses a larger LCD panel and modified electric circuits. The display controller board is also different. The accompanying software application has a more advanced functionality. However, the basic functions and intended use of both systems are the same.

The device does not come into contact with the patient. It does not control any life sustaining devices either.

9. Conclusion:

The Barco Nio Fusion 4MP is substantially equivalent to the predicate device, Color Nio 2MP.

The new and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application and intended use.

Any difference between both devices does not affect safety or efficacy.

The 510(k) Pre-Market Notification for the Barco Nio Fusion 4MP contains adequate information and data to enable FDA – CDRH to determine substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

DEC 29 2006

Mr. Lieven De Wandel
Official Correspondent
BarcoView
35 President Kennedy Park
8500 Kortrijk
BELGIUM

Re: K062905
Trade/Device Name: Nio Fusion 4MP and MDNC 4130
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 13, 2006
Received: December 18, 2006

Dear Mr. De Wandel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K062905

Device Name: Nio Fusion 4MP

Indications for Use:

"The Nio Fusion 4MP is intended to be used in displaying and viewing digital images, for review and analysis by trained medical practitioners. These devices must not be used in primary image diagnosis in mammography.

The Nio Fusion 4MP, containing the display MDNC 4130, the software MediCal QAWeb and the graphic board MXRT 2100, will be marketed as separate device.

Prescription Use __XX___

(Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE (CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K062905

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: MDNC 4130

Indications for Use:

"The MDNC 4130 is intended to be used in displaying and viewing digital images, for review and analysis by trained medical practitioners. These devices must not be used in primary image diagnosis in mammography.

The MDNC 4130, which is part of the Nio Fusion 4MP system, will be marketed separately.

Prescription Use __XX___

(Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE (CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K062905